JUN 2 3 2005

Special 510(k) Summary of Safety and Effectiveness: Line Extension to the Restoration® Modular Hip System

Proprietary Name:	Restoration® Modular System
Common Name:	Femoral Hip Prosthesis
Proposed Regulatory Class:	Class II
Classification:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353, Prosthesis, hip, semi-constrained, metal/polymer, uncemented, 21 CFR §888.3350, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR §888.3358, Hip joint metal/polymer constrained cemented or uncemented prosthesis, 21 CFR §888.3310, Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis, 21 CFR §888.3390, Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, 21 CFR §888.3360.
Device Product Code:	87 LZO, 87 LWJ, 87 JDI, 87 LPH, 87 MEH, 87 KWZ, 87 KWY, and 87 KWL
For Information contact:	Karen Ariemma Senior Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Telephone: (201) 831-5718 Fax: (201) 831-6038 Email: karen.ariemma@stryker.com
Date Summary Prepared:	May 24, 2005

Device Description

The Restoration® Modular Hip System is a modular hip system comprised of different proximal body styles and three distal stem designs, which are affixed with the use of a locking bolt. These individual components are assembled by the surgeon in the operating room or in situ to allow independent sizing of the proximal body and distal stem to better fit the patient. This submission modifies the existing Restoration® Modular Bowed Plasma Stem to create a line extension called the Restoration® Modular Bowed Plasma Trislot Stem. The subject components are for use with the previously cleared Restoration® Modular Distal Stem components.

Indications for Use

The Restoration® Modular System is intended for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. Examples of specific indications for use of the Restoration® Modular System include, non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, rheumatoid arthritis, correction of functional deformity, revision procedures where other treatments or devices have failed, and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Substantial Equivalence

The features of the new components are substantially equivalent to the predicate devices based on similarities in intended use, materials and design. Mechanical testing and analysis demonstrates substantial equivalence of the new components to the predicate devices in regards to mechanical strength. In addition, the intended use, material, manufacturing methods, packaging, and sterilization of the predicate and new components are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2005

Ms. Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corporation
325 Corporate Dr.
Mahwah, New Jersey 07430

Re: K051363
Trade/Device Name: Restoration® Modular System
Regulation Number: 21 CFR 888.3310, 888.3353, 888.3350. 888.3358, 888.3360, 888.3390
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis, Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, Hip joint femoral (Hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: JDI, LWJ, MEH, LZO, LPH, KWZ, KWY, KWL
Dated: May 24, 2005
Received: May 25, 2005

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Restoration® Modular System

Indications For Use:

The Restoration® Modular System is intended for primary or revision total hip arthroplasty, as well as in the presence of severe proximal bone loss. Examples of specific indications for use of the Restoration® Modular System include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Rheumatoid arthritis,
- Correction of functional deformity,
- Revision procedures where other treatments or devices have failed, and
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051363